

**REMARKS/ARGUMENTS**

This is in response to the Office Action dated May 30th, 2006.

Claims 5, 7 and 8 are cancelled. Claim 1-4, 6, and 9-10 are amended. Support for the amended claims can be found in the specification as originally filed. It is believed that no new matter is introduced by the amendments.

Applicant respectfully requests entry of the amendments and withdrawal of the claim rejections.

Priority

Enclosed herein is a certified copy of the Taiwanese application as required by 35 U.S.C. 119(b).

Specification

The corrections of trademarks PEMULEN TR-1NF, CARBOPOL ETD 2020 and CARBOMER have been made in the specification, per the suggestions of the Examiner.

The 35 U.S.C. §102 Rejection

Claim 1 is rejected under 35 USC 102(e) as being anticipated by Ebert, et al. (US 2003/0147926 A1).

Claim 1 has now been amended. Applicant intends to point out the significance of selecting a suitable pH adjuster in a gel formulation of oxybutynin. The use of appropriate alkaline agent is critical in producing a homogeneous and stable gel formulation of oxybutynin. Ebert, et al. disclosed a gel formation of oxybutynin including common pH adjuster such as sodium hydroxide. The potential problem associated with the common pH adjuster is phase separation and lack of stability, particularly at high concentrations of salts and alcohols. The present invention teaches the use of diisopropanolamine, an unique alkaline agent to produce a stable and homogeneous oxybutynin gel formulation. Applicant is unable to find a teaching or disclosure of using diisopropanolamine in the gel formulation of oxybutynin in the Ebert, et. al. reference.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under §102. Because the amended Claim 1 recites the use of diisopropanolamine in the oxybutynin gel formulation, the Ebert et al. reference does not anticipate the claimed invention. For this reason, Applicant submits that amended Claim 1 is allowable over the reference of Ebert, et al.

The 35 U.S.C. §103 Rejection

Claims 1-10 are rejected under U.S.C 103(a) as being unpatentable over Ebert, et. al.


Applicant traverses the rejection as it might apply to the amended claims, and submits that *prima facie* obviousness has not been established. Applicant submits that Ebert, et. al. reference does not teach or fairly suggest all the elements in the claims. Ebert, et. al. teach a topical gel formulation using various common excipients. However, it is silent with respect to the identification and selection of appropriate pH adjuster. Applicant further submits that it would not be apparent to the skilled artisan that selecting the appropriate pH adjuster can significantly improve the homogeneity and stability of the oxybutynin gel formulation.

For these reasons, it appears that *prima facie* obviousness has not been established. Reconsideration and allowance of Claims 1-4, 6, and 9-10 are respectfully requested.

Conclusion

Applicant respectfully submits that the pending claims are in condition for allowance, and notification to that effect is requested. The Examiner is invited to telephone Applicant's undersigned representative if there are any questions relating to this submission.

Respectfully submitted,



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